

REMARKS

The Examiner has imposed an election requirement upon the Applicant's Attorney ("Applicant"). Applicant comments are below.

RESTRICTION

The Examiner is requiring an election of one of the following groups::

- | | |
|-----------|---|
| Group I: | Claims 1-26, 28 and 29, drawn to a liquid formulation for the prolonged release of active principles (AP), comprising an aqueous colloidal suspension of low viscosity based on submicronic particles of water-soluble biodegradable polymer (PO) carrying hydrophobic groups (HG); or |
| Group II: | Claims 27 and 30-34, drawn to a process for the preparation of drugs, particularly for administration by the parenteral, subcutaneous, intramuscular, intradermal, intraperitoneal or intracerebral route or into a tumor, or by the oral, nasal, vaginal or ocular route, characterized in that it consist essentially in using at least one formulation according to any one of claims 1 to 26. |

Applicants elect as follows: **Group I.** This election is made **WITH TRAVERSE.**

ELECTIONS

The Examiner also requires the Applicants to elect an active principle(s), a species of biodegradable polymer (PO) and a species of hydrophobic group (HG).

Applicants elect as follows:

- | | |
|-------------------------------------|------------------------|
| for the active principle (AP): | IFN, |
| for the biodegradable polymer (PO): | alpha-L-polyglutamate, |
| for the hydrophobic group (HG): | alpha-tocopherol. |

This election is made **WITH TRAVERSE.**

Applicants' Traversal

With respect to Applicants' traversal, Applicants respectfully state:

Regarding the Restriction Requirement, the Office Action asserts that "The groups I-II of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons... this technical features is not a special technical features as it does not make a contribution over the prior art in view of Huille et al. (US6,630,171)." Office Action at pages 2-3.

Applicants respectfully submit that the reasons given by the Office Action for the species allegedly lacking the same or corresponding special technical features are improper. Applicants respectfully direct the Examiner's attention to Rule 13.2 of the Regulations Under the Patent Cooperation Treaty ("PCT Rules"), which states

Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. **The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.**

Rule 13.2. *See also* MPEP § 1850, page 1800-96. (emphasis added). Applicants also respectfully direct the Examiner's attention to page 1800-99 of the MPEP, which states

Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims.

* * *

If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention.

(MPEP § 1850, page 1800-99).

Applicants respectfully submit that the independent claims of the application are patentable over the Huille *et al.* reference.

A finding of Anticipation by a reference requires that the reference teach all limitations of the anticipated claims. Huille *et al.* fails to meet this requirement at least because it fails to teach liquid formulations are liquid under injection conditions in the presence of a physiological electrolyte and/or a surfactant, yet form a gelled deposit *in vivo*, which is a feature that is shared by all claims. Accordingly, all of the claims do share a special technical feature and thus do possess unity of invention.

CONCLUSIONS

Applicants believe no fee is due with this response. If a fee is due, however, the Director is authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed (or with any paper filed in this application by this firm) to our Deposit Account No. 50-2228, under Order No. 022290.0159PTUS.

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Respectfully submitted,

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